

PATENT TERM ADJUSTMENT CALCULATIONS CHANGING – WILL THE SUPERNUS PHARMACEUTICALS V. IANCU DECISION STAND?

In *Supernus Pharmaceuticals v. Iancu* (Fed. Cir. 2019), the Federal Circuit reversed the Eastern District of Virginia’s entry of summary judgment that the U.S. Patent and Trademark Office (USPTO) had not erred in calculating the patent term adjustment (PTA) for U.S. Patent. No. 8,747,897 (the ‘897 patent). In particular, the Federal Circuit found the Patent Office’s PTA reduction in the ‘897 patent to be inconsistent with 35 U.S.C. § 154(b)(2)(C)(i).

If the decision stands, it may significantly alter the manner by which the USPTO calculates PTA for some allowed applications. PTA is granted to an applicant to extend the term of a patent in order to account for delays in processing the application at the USPTO. The USPTO can also reduce the number of days of PTA based on delays caused by the applicant during prosecution (i.e., “applicant delay”). In particular, PTA is subtracted for each day the applicant fails to engage in reasonable efforts to conclude the prosecution of the application.

In *Supernus*, the specific rule at issue is 37 C.F.R. §1.704(c)(8), which states that any supplemental reply or other paper (e.g., an Information Disclosure Statement – IDS) submitted by an applicant after a response, unless specifically requested by the examiner, accrues applicant delay. If such a reply or other paper is filed, the PTA is reduced by the number of days between the filing date of the reply/other paper and the filing date of the previous response.

During prosecution of the ‘897 patent, the applicant filed a Request for Continued Examination (RCE) on Feb. 22, 2011. Prior to the issuance of the next Office action, the applicant filed an IDS 646 days after the filing of the RCE. Because the IDS was filed after the applicant submitted the response (and before the USPTO responded), the USPTO characterized the submission of the IDS as a supplemental paper under 37 C.F.R. § 1.704(c)(8), and therefore calculated 646 days of applicant delay in the overall PTA determination.

The applicant challenged the reduction, arguing that they did not fail to engage

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James M. Heinen, Jr.

Rose L. Moller-Jacobs

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in reasonable efforts to conclude prosecution. While the '897 patent was undergoing prosecution, the applicant filed a corresponding application in Europe. The European case granted, and on Aug. 21, 2012, a Notice of Opposition was filed against the European patent. The IDS that the applicant filed on Nov. 29, 2012, cited the information from the European Opposition. The applicant argued that the period of reduction should not include the time period from the day of the RCE filing through the day the Notice of Opposition was filed (546 days). The applicant's position was that they were unaware of any documents to cite in an IDS during this time period, and thus should not be penalized under the statute as failing to engage in reasonable efforts to conclude prosecution.

The Federal Circuit reversed the USPTO and District Court and awarded the applicant an additional 546 days of PTA. The Court stated that "PTA cannot be reduced by a period of time during which there is no identifiable effort in which the applicant could have engaged to conclude prosecution..." *Supernus*, slip op. at 15. Thus, because the applicant did not know of the European Opposition between the time the RCE was filed on Feb. 22, 2011, and the time the Opposition was filed, there was nothing the applicant could have done to conclude prosecution of the '897 patent. The decision highlights that if there is nothing an applicant can do to advance prosecution of an application, the USPTO cannot consider such a submission as applicant delay and reduce the amount of PTA granted.

While this holding involved the filing of an IDS, it has potentially greater ramifications. Applicant delay may be assessed for any number of reasons — some of which may be the fault of the applicant (e.g., filing a response to an Office Action after the three-month date). This decision produces a fact-specific analysis and assessment to determine whether or not an applicant may be entitled to additional PTA. If an applicant believes the assessment of the delay is improper, there are seven months from the date of issuance of the patent in which to petition the USPTO to re-evaluate the assessment (two months, plus a five-month extension).

The USPTO still has time to appeal the decision, so it is possible that it will be reversed or modified. If this decision stands, we expect the USPTO to promulgate new rules/notices to resolve these issues. Patent applicants should work closely with legal counsel to determine how these developments might impact their patent filing strategy.